

## PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number: 20902 Trade Name: PEPCID AC ACID (FAMOTIDINE)GELCAPS 10MG  
Supplement Number: Generic Name: FAMOTIDINE  
Supplement Type: Dosage Form: TAB  
Regulatory Action: AP Proposed Indication: Treatment of heartburn, acid indigestion, and sour stomach. Prevention of meal-induced heartburn, acid indigestion, and sour stomach.

## ARE THERE PEDIATRIC STUDIES IN THIS SUBMISSION?

NO, Pediatric content not necessary because of pediatric waiver

## What are the INTENDED Pediatric Age Groups for this submission?

     NeoNates (0-30 Days )      Children (25 Months-12 years)  
     Infants (1-24 Months) X Adolescents (13-16 Years)

x see comments below

Label Adequacy Adequate for SOME pediatric age groups  
Formulation Status       
Studies Needed       
Study Status     

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

## COMMENTS:

9/10/98 - This NDA provides for a gelatin coated tablet dosage form for OTC Pepcid AC (famotidine, 10 mg). The OTC Acid reducers are labeled down to the age of 12. 8/2/99 - Pediatric studies for below the age of 12 years old has been waived.

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER,  
MICHAEL FOLKENDT

/S/

Signature

Date

8/2/99

## PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number: 20902 Trade Name: PEPCID AC ACID (FAMOTIDINE)GELCAPS 10MG  
Supplement Number: Generic Name: FAMOTIDINE  
Supplement Type: Dosage Form: TAB  
Regulatory Action: NA Proposed Indication: Treatment of heartburn, acid indigestion, and sour stomach.  
Prevention of meal-induced heartburn, acid indigestion, and sour stomach.

IS THERE PEDIATRIC CONTENT IN THIS SUBMISSION? NO

What are the INTENDED Pediatric Age Groups for this submission?

☐ NeoNates (0-30 Days) ☐ Children (25 Months-12 years)  
☐ Infants (1-24 Months) ☒ Adolescents (13-18 Years)

Label Status [Info not filled out]  
Formulation Status [Info not filled out]  
Studies Needed [Info not filled out]  
Study Status [Info not filled out]

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

## COMMENTS:

9/10/98 This NDA provides for a gelatin coated tablet dosage form for OTC Pepcid AC (famotidine, 10 mg). The OTC Acid reducers are labeled down to the age of 12.

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER,  
MICHAEL FOLKENDT

/s/   
Signature

9/25/98  
Date

CSO/Folkendt

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: July 20, 1998

FROM: Michael Folkendt, Regulatory Project Manager  
Division of Gastrointestinal and Coagulation Drug Product, HFD-180

ISI

7/20/98

SUBJECT: Information request, biopharmaceutical

TO: NDA 20-902

NDA 20-902, submitted on September 30, 1997, provides for a chewable tablet dosage form for nonprescription Pepcid AC (famotidine). On July 14, 1998, Dr. Mike Fossler, the biopharmaceutical reviewer, nearing completion of his review, requested the following information to be faxed to him as soon as possible:

1. For Study 085, provide individual  $AUC_{(0-last)}$  and  $t_{1/2}$  values.
2. Is there any multi-point dissolution data available for the [REDACTED] tablet. If so, please provide the data.

These requests were transmitted by phone to Mr. George Latyszzonek of Johnson & Johnson Merck Consumer Pharmaceutical Company (215-233-7152) on July 14, 1998.

On July 17, 1998, Mr. Latyszzonek notified me of the following:

1. It will take a couple of weeks to put together and submit the  $AUC_{(0-last)}$  and  $t_{1/2}$  data.
2. There are no multi-point dissolution data available for the [REDACTED] tablet.

I passed on Mr. Latyszzonek's response to Dr. Fossler who, in the interest of completing his review promptly, requested that the request for individual  $AUC_{(0-last)}$  and  $t_{1/2}$  values be cancelled stating that he would compute these values himself. On July 20, 1998, Mr. Latyszzonek acknowledged and accepted cancellation of the request for individual  $AUC_{(0-last)}$  and  $t_{1/2}$  values.

There is no other pending request of the firm at this time.

cc:

Archival 20-902  
HFD-180/Div. Files  
HFD-180/M.Folkendt  
HFD-870/M.Fossler

MEMORANDUM